reproducibility.
Finally, in violation of Executive Order 12866, the proposal fails to perform any analysis regarding the impact this rulemaking could have on the environment, public health or science generally -- or even on what it would cost to implement. Because the Agency does not have authority to undertake this effort, and because it would undermine the consideration of relevant science in its public health and environmental rulemaking, it should be abandoned. Thank you.
MS. RADZIKOWSKI: Thank you. I'd like to remind speakers to please speak into the microphone.
MS. ROSEN: Good afternoon, this testimony is on behalf of Lynn Goldman. She is a pediatrician and an epidemiologist and has been Dean of the Milken Institute School of Public Health at the George Washington University since 2010 and former Assistant Administrator for Toxic Substances at the US Environmental Protection Agency. My name is Erika Rosen and I am delivering this oral testimony on her behalf. Her full written

comments will be submitted for the record. This proposal suffers from lack of involvement of the scientific community, either within or outside of the EPA. No clear justification is given for why it is needed. The proposed rule is a dramatic departure from how the EPA and other US regulatory agencies, as well as similar agencies internationally, use science for the development of dose response assessments. It ignores a number of adverse downstream consequences including: risking disclosure of personal information of people volunteering for human subjects' research; delaying EPA decision. making; exacting unknown but probably considerable costs to the research community and to the EPA; and making best available science unavailable to the EPA. It creates no regulatory authority or any other mechanism for the EPA to compel submission of data from academic scientists and industry, other than those that already are accessible under the Information Quality Act of 2001, nor a mechanism for access to industry data claimed as

Confidential Business Information. It creates an unfortunate precedent for EPA in the creation of science policy by rulemaking. The proposal ignores the "systematic review" methods for review of evidence that have been developed, refined and improved over a number of years in the context of IRIS, pesticides, toxics, and priority air pollutants. The application of such methods has been reviewed and improved upon by the National Academy of Sciences and the National Toxicology Program. Of note is no authoritative body of experts has ever recommended requiring "raw data" in order to perform or review dose response assessments.

Risk assessment activities at EPA are extensive and its programs are performing more than 1,000 risk assessments per year. The proposal does not consider the costs, the significant time and paperwork burdens, and major regulatory delays that will occur when EPA is waiting for data to be made publically available, which may not ever happen.

For years, both Congress and successive administrations have required the EPA to use the best science for its decisions. Directing EPA scientists to exclude key studies is not consistent with good scientific practice and is contrary to years of effort to improve the base underpinning EPA's decisions.

The proposal misrepresents the recommendations of prior expert reviews such as the so.called NAS "Silver Book" and the Bi.Partisan Commission review. It is oblivious to NAS conclusions that thresholds of chemical exposure for chemical effects are the exception rather than the rule. Single studies are used to inform risk assessors of the possible shape of dose response curves. Instead, EPA evaluates all of the scientific information to gain a biological understanding of the "mode of action". When data do not prove mode of action, EPA often applies default assumptions such as low dose linearity for carcinogens, and certain noncancer effects that have no practically identifiable thresholds.

This proposed rule for the first time opens the door to EPA's scientific practices being determined by regulators, and not scientists. This is a rush down a slippery slope that would replace a scientific process with a political one and would freeze the science in procedures that certainly will not be scientifically defensible in the future. This is a breach of the fundamental notion of separating risk assessment from risk management.

I strongly urge the EPA administrator: (1) not to use the Agency's regulatory authority to prescribe specific risk assessment processes; and (2) not undertake changes in EPA's science policies without leadership from EPA scientists and full engagement of the science community. What is at stake is no less than the credibility of the Agency with the American public and public confidence in the integrity of EPA's science and decisions.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker 11, Gretchen Goldman, and

Speaker 12, Maggie Flaherty, if you would come to the stage. Speaker 13, Adam Finkel, and Speaker 14, Augusta Wilson, if you'll come to the on-deck seating.

MS. GOLDMAN: my name is Gretchen Goldman, G-R-E-T-C-H-E-N, G-O-L-D-M-A-N. I'm the Research Director at the Center for Science and Democracy at the Union of Concerned Scientists, and I'm also a mom. As a scientist, I'm deeply troubled by this proposal. As a mom, I'm alarmed by it, and the risks that it poses to my children and others. The EPA's mission is to protect public health but this proposal does the opposite. This proposal needlessly restricts the science that EPA can use to make decisions about all of our families' health. Many crucial scientific studies that rely on public health data, intellectual property, confidential business information and other scientific information that may not be publically acceptable would be unavailable to EPA experts under this proposal. As a result, the EPA will be prevented from making rules that protect people

using the best available science. There is no reason for such a rule. The EPA already follows a rigorous, science-based process for determining when and how studies are used in its decisions. I've seen this first-hand when the EPA contacted me about my own scientific research. The Agency needed to obtain results data from my peer-reviewed studies looking at ambient air pollution exposure in time series' epidemiologic studies. I can attest to the fact that the EPA already ensures it is using reliable and robust scientific information to make decisions. When my son was born he spent five days in the neonatal intensive care unit because of a respiratory problem and when I took him home I knew it would be important for me to make sure that he could breathe clean air. I can't protect him from the air outside always but the EPA can. When my children breathe outside I need to know that the air is healthy. When my children play in the grass I need to know that there aren't harmful pesticides in it. When my children drink from their sippy cups, they need

to know -- I need to know that the water is safe. How can EPA scientists protect my family and others if they can't use the best available science?

I urge you to withdraw this proposal and instead focus on EPA's mission of ensuring safe water, air and land for people across the country. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. FLAHERTY: Good afternoon and thank you for the opportunity to speak today. My name is Maggie Flaherty, F-L-A-H-E-R-T-Y, and I would like to express my strong opposition to the proposed, "Strengthening Transparency in Regulatory Science" rule. I would first like to emphasize that this rule proposed during Scott Pruitt's time as administrator of the EPA is a purely political decision. It is modeled after past efforts from the tobacco and fossil fuel industries for similar policies that prevent the use of science that reveals the harmful human health impacts of such industries. This proposed rule is not about

legitimate transparency; it is about making it harder for the EPA to make decisions based on the best available science. Under this rule studies that rely on personal health data, confidential business information, intellectual property, or studies whose data is no longer available would be excluded from the EPA's consideration when making decisions regarding regulations. When it comes to regulating things such as air pollution, water pollution and toxic substances, some of the most vital scientific information comes from studies of respiratory illnesses, cardiovascular diseases, and premature deaths, all of which rely on personal health data. If such vital studies are excluded because of this arbitrary rule, the EPA would be lacking critical public health information when making decisions that directly impact our health and environment.

If EPA is truly worried about transparency in science they would listen to the voices of the numerous scientists who have come out in opposition to this proposed rule and who have,

additionally, suggested other ways of introducing transparency. Instead of focusing on disclosure of data that can contain confidential and private information, a rule that truly increased transparency in science would focus on funding disclosure. Despite how strict the peer review process is, people should be able to know who is funding a study. This rule proposed by the EPA does not address the issue of funding transparency at all. According to an article in the Journal of the American Medical Association if all of the EPA's proposed changes to environmental policies since the election of President Trump go into effect, the result would be at least 80,000 unnecessary deaths per decade. This assessment is based on numerous scientific studies that would most likely be excluded by this rule. The EPA should not exclude studies that demonstrate the true health costs of their actions and remember their true mission of protecting our public health and the environment. I therefore urge the EPA to withdraw this proposed rule. Thank you.

MS. RADZIKOWSKI: Thank you.
MS. STOBERT: If Speaker 13, Adam Finkel, and Speaker 14, Augusta Wilson, will come to the speakers' table. Speaker 15, David Coursen, and Speaker 16, Abigail Omojola would come to the on-deck seating.
MR. FINKEL: Thank you. I appreciate the opportunity to comment as a former chief regulatory official at OSHA and a former member of the EPA Science Advisory Board and Board of Scientific Counselors. I support a wide spectrum of efforts to improve the transparency of the inputs to and the outputs of risk assessment and cost-benefit analysis, especially if they involve a more honest disclosure of uncertainty and variability. I will submit a recent paper I wrote with George Gray in this regard. But this proposal decreases transparency and reliability in three ways: It fails to identify a legitimate problem; it ignores closely related and glaring actual problems with regulatory analysis; and it promotes remedies that add noise while decreasing

signal.

First, the central dogma of regulatory policy since 1993, and most enthusiastically touted by this administration, holds that no regulation can be proposed absent a real problem to be solved, like market failure. Here, there is no failure of the scientific market and hence no need for a disruptive set of hurdles. By its own policies it developed to constrain its own regulatory excess, EPA should demonstrate, and not just with an anecdote or two, the crisis justifying the need for this proposal, or else should scrap it. I note that of the five URLs the EPA provides in Footnote 12 to document its claim that there is a "replication crisis," two of the links are broken and the other three discuss psychology and clinical trials. The end points in epidemiology, toxicology and exposure studies are simply not as subjective as psychology experiments are. There have been some problems found with clinical trials but the unmeasured variability is likely much more important with respect to whether a drug will cure

and weather a pollutant will harm. Most importantly, the EPA has cited no studies giving even guesstimate of what percentage of environmental science studies might be in need of replication or reanalysis and, of course, some of the shrill prior claims of error others have noted in the Six Cities Study have turned out to be fallacious. Surely EPA does not intend that most epi studies or bio-assays need to actually be replicated. Some epi studies can be redone but surely not natural experiments we never want to repeat such as the atomic bomb survivors study or the changes in air pollution during groundings right after 911. Lifetime animal bio-assays already use multiple doses, species and sexes and they are expensive and take years to complete. Why would we waste time and money duplicating them? And so, what if someone did try another species and got a lower potency estimate or didn't get positive results? Would we allow a rat or mouse carcinogen in unlimited quantities because it might not also be an aardvark carcinogen? I

don't think so. So, EPA probably means reanalyze, not replicate, and it should say so. But then EPA presents no evidence that anyone is hindering anyone else from reanalyzing anything. Any bio-acid that the EPA would use would already have individual tumor data and exposures and could be reanalyzed with any model that anyone wanted. Ditto for epi studies. But what would a reanalysis program actually do other than be costly and invite delay? What if someone reanalyzed a health study and got a different answer? One that suggests the first study had exaggerated the harm. In such a case the second study would be right and the first wrong only if both of these conditions were true. First, the difference in the results was not already acknowledged or contained within the uncertainties in each answer. If somebody claimed that banning a chemical would save between 500 and 1000 lives across the country, EPA chose to estimate it at an expected value of 750; another study that said 550 would not be different from the first study at

all. And secondly, the first study would have to be not just different, but wrong. Anybody can take the same data and botch the risk analysis of it making seem like they have a better answer. Just like there are potential problems with an analysis that doesn't control for some variable, it can be a mistake to control for a variable that shouldn't be included.

In short, EPA should never refuse to look at a study just because someone could reanalyze it but hasn't, has done so and gotten a different but not a better answer, or has done so, didn't like what it saw, and suppressed the results while claiming the original study still needs to be reanalyzed. Secondly, there is a crisis in regulatory analysis and EPA is completely ignoring it for reasons that are obvious to me. It's the economists' analysis of the costs of regulation and the values of benefits that are flawed, opaque and in need of reanalysis. Every criticism leveled at this proposal ought to first be applied to regulatory economics. They are obviously as pivotal as

estimates of risk. Regulatory cost estimates are notoriously biased high and they are surrounded by more uncertainty than surrounding risk estimates, but unlike risk estimates, cost estimates are rarely, if ever, presented with uncertainties and are sometimes even of the wrong side. In my written comments I'll give two examples. I have a paper newly published with Brandon Johnson. We looked at more than 1000 estimates, the value of a statistical life, certainly the most pivotal quantity in all of risk regulation derived from hundreds of studies. Only 40% of those studies gave any information about the ranges or standard deviations of the individual VSL values. So, no one can reanalyze that work to see what higher or lower values of the VSL are also compatible with the data. And perhaps the most well-known so-called study of the costs of regulation is the series of reports from Mark and Nichole Crane suggesting that regulations "cost the U.S. nearly two trillion dollars a year."

MS. RADZIKOWSKI: Excuse me, sir, we are out of

time.

MR. FINKEL: I'm sorry?

MS. FLOWERS: We are out of time, in fairness to others.

MR. FINKEL: I'm sorry, I didn't realize. The third one is about defaults and I will submit those, but EPA is a protection Agency, not a prediction Agency. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. WILSON: Good afternoon, my name is Augusta Wilson, and I am here representing the Climate Science Legal Defense Fund. The first name is spelled A-U-G-U-S-T-A. I appreciate the opportunity to speak to you today and the Climate Science Legal Defense Fund will file more detailed written comments in the online docket for this proposed rulemaking. CSLDF is a nonprofit organization whose mission is to protect the scientific endeavor. In this capacity, we work closely with scientists at government agencies and at research institutions, so we have particular insight into how attempts to silence science

negatively impact both researchers on an individual level and the conduct of scientific research as a whole. There are numerous reasons why EPA should not proceed with this rule. In the time I have today I will focus on a few of the most important from the perspective of protecting the integrity of the scientific endeavor. First, studies that involve human subjects, particularly those investigating the human health impacts of exposure to environmental pollutants, are among the most relevant to EPA's core mission. In order to conduct such studies, scientists need participants willing to allow researchers access to their confidential health information. If enacted as currently proposed, this rule would make it much more difficult for scientists to credibly promise study subjects that their patient information will remain confidential. This could have deeply concerning, chilling effects on the conduct of important human health studies. Privacy concerns could influence what science gets done and what science does not get done. Lines of

scientific inquiry that would have been pursued may not be. The quality of data may be poorer than it otherwise would have been. Furthermore, the justification for this rule to the extent it exists seems to be based on the false premise that scientific studies cannot be adequately evaluated or reproduced unless all of their underlying data are made public. This is simply not the case. On the contrary, the reviewers can evaluate the merits of studies even when they rely on data that cannot be made publically available. This is because part of a scientist's core, fundamental training is the ability to assess research based on the strength of the experimental design and the precision with which experimental methods and analyses are described. In addition, when necessary and appropriate, reviewers, as well as other researchers seeking to reproduce or extend scientific analysis, can have confidential access to key data in conformity with privacy requirements.

That said, the scientific community has certainly

recognized that recent technological developments allow for significant improvements in data sharing and reproducibility and that such improvements can benefit science. There are numerous scientific societies, journals, and other organizations, as well as individual researchers, who are actively engaged in a dialogue about how to improve transparency while protecting scientists and taking into account issues like patient confidentiality and proprietary business information. If EPA is genuinely concerned about these issues, it should engage deeply in this discussion and with the scientists who are having it and should move forward only in concert with them. As written, this rule which EPA professes is intended to strengthen science will ultimately do significant damage to it and to the United States' ability to lead the world in research. EPA should not promulgate such a rule. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: If Speaker 15, David Coursen, and Speaker 16, Abigail Omojola, would come to the

speakers' table. Speaker 17, Alan Lockwood, and Speaker 18, Elizabeth Woolford, if you would come to the on-deck seating.

MR. COURSEN: Good afternoon. My name is David Coursen, C-O-U-R-S-E-N, and I'm here on behalf of the Environmental Protection Network, a nonprofit organization of EPA alums working to protect the Agency's progress toward clean air, water, land and climate protection. There are so many things wrong with this proposal that it's easy to downplay the most important one: The harm it will do to peoples' health and the environment. The proposal hides this in a fog of ambiguous language, meaningless generalities and vague platitudes about the value of transparency. It requires EPA to wear a blindfold when it is developing major rules by ignoring what relevant and reliable science tells us about health risks any time the raw supporting data is not publically available. Transparency is important, but it is not part of the Environmental Protection Agency's mission and certainly cannot be the basis for a

one-size-fits-all litmus test for when the Agency must ignore what science tells us about the risks of pollution.

The laws governing EPA programs require it to consider all of the available scientific information in deciding how to protect peoples' health and the environment. Ignoring such information would be both arbitrary and unlawful. EPA rulemaking has always relied on the best available science, a principal the proposal gives lip service even as it outlines a scheme to prevent the EPA from using even the best available science if it is not "transparent." The proposal would put even the most persuasive and useful science off limits subject only to a vague and standardless exemption process. The proposal does not show that the EPA's existing practices have produced bad environmental outcomes or that increasing so-called transparency will lead to better outcomes. Those are not things the proposal seems to care about. There is no legal or environmental basis for the proposed

restriction and, not surprisingly, the proposal fails to mention that EPA's statutes do not allow the Agency to ignore available information about the risks of pollution. Inevitably, restricting the science EPA considers in rulemaking will produce less informed and less protective decisions. In effect, the proposal sacrifices relevant and reliable scientific information, a cornerstone of effective environmental protection on the altar of so-called transparency. A proposal to ignore science when all of the supporting data is not public would preclude using even recent studies that are subject to confidentiality agreements or legal restrictions on disclosure. It also will certainly and deliberately exclude older studies where the data is no longer available, even if their findings are widely accepted as authoritative and form the basis for EPA regulations that have proven effective in protecting peoples' health for many years.

The proposal is evasive about its targets using

footnote language only a lawyer could understand to identify two seminal air pollution studies that it excludes and says nothing at all about what other important studies it would ban. Written comments via the Environmental Protection network will spell out the policies that proposes many legal and policy defects in detail. The proposal is brief and cursory and provides far too little information to meet the legal requirement to alert the public to its substance and basis. It would prohibit EPA from considering important science in rulemaking even though the laws governing EPA's use of science require it casting a wide net. It sheds little light on how the proposal would work and no light at all on its environmental consequences. Instead of explaining how EPA will implement and interpret the rule, it largely throws these questions to the public. It doesn't show a need for any rule much less an absolute rule that sweeps across eight statutes. It claims its approach is consistent with a host of policies and studies but what Environmental Protection

Agency looked at them it found almost no support for the proposal and in some cases the authors have objected to the use of their studies and it posed the proposal. In sum, there is neither a legal basis nor a need for this rule. It would require the EPA violate explicit statutory provisions and unlawfully shifts the basis for deciding what science to use in rulemaking away from the statutory goals of reliability and environmental protection to so-called transparency, a term not found in the relevant EPA statutory provisions. It is too full of undefined or ambiguous terms to create a workable legal frame work. In other words, the proposal is unintelligible, unlawful and unworkable. EPA, I respectfully request that EPA withdraw it.

MS. RADZIKOWSKI: Thank you.

MS. OMOJOLA: Good afternoon, my name is Abigail Omojola, O-M-O-J-O-L-A, and I am here on behalf of Breast Cancer Prevention Partners to speak in strong opposition to the proposed rule and to urge the EPA to withdraw it immediately.

Breast Cancer Prevention Partners is a national organization committed to preventing breast cancer by eliminating exposures to chemicals and radiation that have been linked to an increased risk of the disease. We take great care and pride in ensuring that all of our public education, programs and policy advocacy are based on a strong foundation of peer-reviewed science.

Contrary to its stated intent, the proposed rule under consideration today would not serve to provide the public with greater "confidence in and understanding of" EPA's regulatory decisions. Rather, it would deeply undermine the ability of the EPA to use all the best available science in its regulatory decisions, which, in turn, will negatively impact public health. In fact, it is hard not to come to the conclusion that the proposed rule is a strategy to disregard many studies that have shown negative impacts of chemical exposures on public health.

Breast cancer is a disease with complex causation and often a long latency period. Only about 10% of

breast cancer diagnoses can be attributed solely to genetics. Breast cancer risk is a web of interactions between environmental exposures, genetics and lifestyle characteristics. Much of the data showing the connection between unsafe chemical exposures and breast cancer risk comes from laboratory studies. However, epidemiological studies, and in particular longitudinal studies, provide unique insights and important corroboration of these findings.

The proposed rule's requirement that underlying data must be made public before the EPA can consider a study in agency decision-making will have the practical impact of eliminating many of these critical studies from the regulatory process. Epidemiological studies involve the collection of extensive and detailed individual health data and researchers have an ethical obligation to protect the confidentiality of that data. The elimination of these studies will result in less scientifically sound conclusions and, most importantly, the public health benefits they would

provide.
An example of the kind of study this proposed rule could eliminate from the EPA's regulatory process is the National Institute of Environmental Health Sciences' Sister Study. From 2003 to 2009, the Sister Study enrolled 50,000 women whose sisters had breast cancer. Those women will be followed for a minimum of 10 years to study how genes and the environment interact to impact the risk of developing breast cancer, leading to a greater understanding of ways to prevent both breast cancer and other diseases. It does not serve the public interest to hinder the EPA's ability to use this type of research in their regulatory decisions.
This proposed rule will not only undermine the use of previously conducted epidemiological studies; it will also damage the ability of researchers to conduct future studies. Recruitment of study participants will be severely undermined if people fear their personal information may be made publically available. This is particularly true

for vulnerable marginalized communities that are both disproportionately exposed to toxic chemicals and have historical reasons to distrust researchers. Yet, it is the exposures experienced by these communities, and the resulting health effects, that we most need to understand and address.

The integrity of scientific methodology is thoroughly reviewed at many points in the processes of designing, conducting and publishing scientific research already. There is the competitive grant process; Institutional Review Board requirements; peer-review prior to publication; the expertise and judgment of career EPA scientists when considering the strength and relevance of studies included in EPA decisions; and finally review of those decisions and the underlying science by EPA's Science Advisory Board; all provide more than sufficient opportunities to assess the soundness of scientific studies. This proposed rule is not only damaging, it is unnecessary.

On behalf of the 1 in 8 women who will be diagnosed in their lifetime and the 40,000 lives that are lost each year in the U.S. to breast cancer, the EPA has an obligation to take action to prevent this devastating disease. This proposal takes a hard step away from that goal.
Thank you for the opportunity to provide this public comment urging the EPA to withdraw this misguided and damaging proposed rule.
MS. RADZIKOWSKI: Thank you.
MS. STOBERT: If Speaker 17, Alan Lockwood, and Speaker 18, Elizabeth Woolford will take seats at the speaking table. If Number 19, Paul Allwood, and Speaker 20, John Stine, would take seats at the on-deck seating.
Mr. LOCKWOOD: Good afternoon, my name is Alan Lockwood, A-L-A-N, L-O-C-K-W-O-O-D. Thank you for this opportunity to speak on behalf of Physicians for Social Responsibility. I am a board-certified neurologist and an elected fellow of the American Neurological Association and the American Academy of Neurology, and Professor Emeritus of Neurology

at the University at Buffalo. PSR is a 501(c)(3) scientific and educational organization headquartered in Washington DC with over 30,000 physicians, medical students, and others across the country. Our mission is to protect human life from the gravest threats to health and survival. We submit this testimony in strong opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." The proposed rule would change the standards for the inclusion of studies used by the Agency and lead to the abolition or weakening of virtually all protections under the purview of the Agency. Under the misleading veil of "transparency," the proposed rule could force investigators to invade the confidentiality of research participants and make confidential and private data open to all. A similar concern was voiced by the current Scientific Advisory Board, writing, "there are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests ..." The rule could replace evidence-

based decision-making with arbitrary determinations based on political considerations. Peer-reviewed research has led to important gains in health. The Clean Air Act protects us from air pollution and is arguably the most health-protective law in effect. I have written extensively about this in The Silent Epidemic. Peer-reviewed studies link air pollutants with leading causes of death in the United States including heart disease, stroke, and respiratory diseases. Additional studies link particulates to Alzheimer's disease and Type II Diabetes. Seminal studies include the Harvard Six Cities Study that involved 8,111 adults followed for between 14 and 16 years showing a clear link between pollution and mortality. The Women's Health Initiative study involving 65,893 post-menopausal women that demonstrated a link between particulates, and cardiovascular disease and stroke mortality. I attended closely to the study of 1,705 neurologist-confirmed strokes showing that a transient increase in small particles was

associated with a statistically significant increase in strokes even though levels were within limits "generally considered safe" by the EPA. A congressionally mandated report prepared by the EPA projected that by 2020 Clean Air Act provisions would save two trillion dollars per year in adverse health impacts. Many savings will positively impact the budgets of state and federal agencies at a time of ballooning deficits.

EPA rules provide significant protection for the developing brains of children by establishing limits on lead. Lead impairs brain development and has adverse effects on behavior and cognition. Other data link arsenic levels in drinking water to Type II diabetes and cancer.

Natural gas production, particularly "fracking" harms health due to human proximity to wells, pumping stations, and contamination of water supplies and contributes to climate change.

Protecting the privacy of research participants is a keystone of biomedical research and one with which I have had years of personal experience as a

member then chairman of the Buffalo VA Institutional Review Board. Peer-reviewed journals require authors to affirm their adherence to federal privacy protections as a pre-condition for publication. This standard should not be abolished. PSR's mission is to "to protect human life from the gravest threats to health and survival." To protect the scientific integrity of the EPA and protect health, we oppose the deceptively named proposal, "Strengthening Transparency in Regulatory Science." Thank you.

MS. RADZIKOWSKI: Thank you.

MS. WOOLFORD: My name is Elizabeth Woolford and I am an undergraduate student at Wesley University and an intern with the National Parks Conservation Association. My comments are my own. Today, I would like to express my strong opposition for the proposed rule titled, “Strengthening Transparency in Regulatory Science.” This rule would have sweeping impacts on the ability for the EPA to consult public health studies, as almost all utilized data from medical records that are

protected from public scrutiny. Their proposal would force the Agency to disregard such studies unless scientists reveal their participants' private medical information. Scientists conducting public health research would then be left with two unacceptable options: To break confidentiality agreements in order to disclose the personal health records of their subjects; or not to have their studies consulted by policy makers at all. As a result, some of the most significant research from the past decade, for example studies linking air pollution to premature deaths and measuring human exposure to pesticides would be left completely unavailable to the Agency. I would like to emphasize that data of a sensitive nature does not imply inherent unreliability, rather this kind of information is essential to achieve an accurate understanding about how human health is impacted by chemicals, chemical compounds and other substances. Such an understanding is necessary for the EPA to fulfill its mission to protect public health and protect

the environment with the creation of effective regulations under the Clean Air Act, Clean Water Act, CERCLA, and other cornerstone environmental laws.

This proposal is based on a false premise about data quality and acceptability. There is no reason why one cannot protect the confidentiality of subjects and at the same time use information about them. This rule questions the integrity of the scientists and doctors conducting public health studies by implying that these professionals may have biased their subjects to achieve a particular outcome. However, it is evident that peer review already protects against for such bias.

For these reasons, one must consider how this proposal fails to achieve the requirements of OMB's Information Quality Act. It is clear that this proposal is overkill and would unnecessarily exclude scientific studies simply because they do not meet an unrealistic transparency standard. This would all be to the detriment of public and

environmental health.
In addition, this rule would create a blatantly political and dangerous double standard by eliminating the use of studies that follow confidential health guidelines while allowing polluting industries to keep their data under wraps. That alarming imbalance would skew regulation inherently favoring polluters over those impacted by their pollution.
Furthermore, this proposed rule would cross Agency lines and interfering with informed policy making and undermining the safeguards that protect millions of people, our public lands, and the space and places we call home. EPA's scientific research and related policies influences the decisions of other agencies charged with protecting our health and environment. For example, the National Parks Service needs access to the best available science to inform decisions that protect parks' air, land, water, wildlife and people. If EPA goes forward in placing unreasonable limits on the scientific record, the

National Parks Service and similar agencies will be unable to protect public health and the environment to the extent they otherwise could. As a young person, this proposal leaves me frightened. Within a decade I will be part of the generation that inherits the responsibility for this nation. If adopted, the negative implications of this rule will not be short-lived and could forever change the safeguards that EPA is supposed to develop to protect public health and our environment. In the many more decades of life I have in front of me, I intend to finish my education in this country, I intend to raise a family in this country, I intend to enjoy public lands and outdoor spaces in this country, and I intend to breathe this country's air and drink this country's water and eat this country's food. I hope to do so knowing that the regulatory body charged with keeping my body and environment safe has made decisions based on nothing less than the best scientific information there is. For these reasons, I urge the EPA to abandon this dangerous

and misguided proposal. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker Numbers 19 and 20, Paul Allwood and John Stine, if you would take seats up here. And Speaker Number 21, Virginia Ruiz, and Speaker 22, Karen Mongoven, if you would take seats the on-deck seating.

MR. ALLWOOD: Good afternoon, my name is Paul Allwood. I am Assistant Commissioner of Health Protection at the Minnesota Department of Public Health. Commissioner Stine is with me and we're going to do this joint testimony. Commissioner Stine will go first.

MR. STINE: Thank you. As Commissioner of the Minnesota Department of Health, Mr. Allwood is the Assistant Commissioner there, and as Commissioner of the Minnesota Pollution Control Agency, my name is John Link Stine, S-T-I-N-E. We are appointees of Minnesota's Governor, Mark Dayton. We are deeply disappointed in and troubled by this proposed rule, "Strengthening Transparency in Regulatory Science." We have traveled 1100 miles

from our home in Minnesota to be here today to speak against this rule. On May 15, 2018, our two state agencies commented against this rule in a letter from Commissioner Malcolm of the Health Department and myself. Our testimony today expands upon those comments and provides specific examples from Minnesota that show why this arbitrary and non-ethical rule must not be adopted.

MR. ALLWOOD: The first example is that the State of Minnesota is dealing with a massive area of contamination with PFAS chemicals, otherwise known as PFCs. The contamination came from 3M Manufacturing and disposal sites that contaminated groundwater on a very massive scale impacting over 150,000 residents. Minnesota's Department of Health conducted bio-monitoring studies of over 200 people living in those impacted communities to be able to understand their exposure and their potential health implications. Those studies help Minnesota derive health protected values under state law and furthermore also help the state of

Minnesota reach a settlement with 3M Company of over 890 million dollars. Now, without these studies and without these data we would not have been able to be successful in our litigation with 3M Company and residents of the communities that were impacted by this pollution would have had to foot this bill.

Now, these studies are only possible because we provided absolute guarantees to the participants that their data would be protected and that we would assure its confidentiality. The proposed rule will make it unlikely that public health data such as this -- and you heard it from other testifiers -- would be available for states to use, but even more so for the EPA to use in its decision-making. This is to be avoided.

MR. STINE: Our second example is the 2015 study and report that our agencies jointly released "Life and Breath". We released that report regarding the health impacts of air pollution in the Twin Cities Metropolitan Area of Minneapolis and St. Paul. The study used public health data

and mathematical modeling software developed by the U.S. EPA. EPA's modeling software is based on published, peer-reviewed scientific studies of the relationship between human health and air pollution. The study confirmed air pollution leads to increased disease and death in our population. Every year about 2000 premature deaths, 400 hospitalizations and 600 emergency room visits occur in the Twin Cities Metropolitan Area that are caused by fine particle or ground-level ozone exposure. In fact, the study found that fine particle air pollution and ground-level ozone was a causal factor for some deaths and hospital visits for lung and heart conditions. The implications of the proposed rule are that under this rule's requirement for the use of public data, future public health data on which studies like our "Life and Breath" were based would not be available. Public health data and research relies on citizen confidence in confidentiality of their personal information. We believe the rule would lead to an over-reliance

on animal studies and toxicological data which cannot estimate disease burden as well as population health data and studies. The proposed rule would lead to weaker environmental regulations, more air pollution, greater levels of heart and lung disease and death. As a result, health care costs will increase. Asthma already costs the United States 56 billion dollars annually and the incidence of asthma is increasing. The rule language under Part 30.8 requires that EPA implement the rule in a manner that minimizes cost. Ironically, the rule will lower the cost to EPA and environmental polluters. A fundamental principal of our environmental protection law is that polluters pay. The plain truth is that your rule does not address the increased costs that come with relaxed regulations. In fact, the polluters will pay less and costs will shift onto the public in health insurance. With that I'll kick it to Mr. Allwood.

MR. ALLWOOD: So, to conclude, to say that state as public officials we are responsible for

protecting the health of our state population, it's really important for us to be assured that EPA is going to use the best science in its regulatory decision-making. This rule severely brings that into question and we would like you to know that we are looking at this as an urgent matter that requires the EPA's attention and would urge that time be taken to suspend and slow the process of adopting this rule so that a full and complete review can be done. Thank you.

MR. STINE: Thank you.

MS. RADZIKOWSKI: Thank you both.

MS. STOBERT: Speaker 21, Virginia Ruiz, and Speaker 22, Karen Mongoven, if you would come to the speakers' table. Speaker 23, Steve Milloy, and Speaker 24, Steve Milloy for John Dunn, if you would have seats at the on-deck seating?

MS. RUIZ: Good afternoon, my name is Virginia Ruiz. I am the Director of Occupational and Environmental Health at Farmworker Justice, an organization devoted to working with migrant and seasonal farmworkers to improve their living and

working conditions. On behalf of my colleagues at Farmworker Justice and the farmworkers that we represent, I strongly urge the U.S. EPA to withdraw its proposed rule, "Strengthening Transparency in Regulatory Science." If finalized, this rule would endanger farmworkers and other vulnerable people across the country. We oppose EPA's proposed rule for three reasons: First the rule would prohibit EPA from considering credible scientific evidence about the dangers farmworkers face including exposure to pesticides and other chemicals. Second, the rule would deter farmworkers themselves from participating in future scientific studies. Third, the rule would make it more difficult for Farmworker Justice to obtain the research we need to advance our mission. With respect to the first point, the proposed rule would prohibit EPA from considering credible scientific evidence about the dangers that farmworkers face. As EPA's own Science Advisory Board acknowledged, there are many reasons why researchers and study participants

might choose to keep data confidential, and many of these reasons have no bearing on the credibility of a scientific study. For instance, because farmworkers are often migratory, moving for work across domestic and international borders, researchers may be unable to locate farmworkers they last encountered as study participants years ago, and thus unable to renegotiate privacy agreements struck at the time the research was conducted. Farmworkers themselves may also have legitimate reasons for wanting to preserve their privacy. For example, some research shows that farmworkers face an increased risk of exposure to chemicals that impair fetal development resulting in lower IQ scores, an outcome associated with significant social stigma. We already suffer from the dearth of scientific evidence and information about occupational and environmental health risks that farmworkers face. EPA should base its regulatory decisions on the credibility of scientific evidence and not on arbitrary factors like the

public availability of research data. With respect to the second point, the proposed rule would deter farmworkers from participating in future scientific studies. Farmworkers are extremely vulnerable members of our society and it's unlikely they would agree to participate in scientific research without an iron clad guarantee that their identities would be kept confidential. Farmworkers value their privacy for a number of reasons including an undocumented or other tenuous immigration status and insecure employment. Farmworkers whose identities are exposed would risk retaliation from their employers ranging from termination to deportation. As a result the proposed rule would present farmworkers with a false dilemma. They could choose to participate in research studies that might eventually yield better regulatory protections at great personal risk, or they could choose to protect their privacy by refusing to participate in research studies, thus forgoing badly needed protections, also at great personal cost. EPA should not

present farmworkers with such a choice. Finally, the rule would frustrate Farmworker Justice's ability to achieve our mission. We rely on credible scientific evidence to educate farmworkers, policy makers and the public at large about the risks farmworkers face. Much of this evidence comes in the form of epidemiological studies that the proposed rule would categorically exclude from consideration unless the underlying data were made publically available. If EPA's proposed rule were to result in fewer scientific studies focusing on farmworkers, as seems inevitable, we would lack information we need to carry out this important aspect of our mission. It would severely undercut our ability to effectively advocate for farmworker health and safety.

Accordingly, we urge EPA to protect farmworkers and other vulnerable communities by withdrawing the proposed rule without delay.

MS. RADZIKOWSKI: Thank you.

MS. MONGOVEN: Good afternoon, I'm Karen Mongoven;

K-A-R-E-N, M-O-N-G-O-V-E-N, Senior Staff Assistant at NACAA, National Association of Clean Air Agencies, and I appreciate the opportunity to testify today on behalf of NACAA. NACAA recommends that EPA withdraw this proposed rule. In our view the proposal would likely undermine the very objectives that it's supposed to promote. In particular, we believe it would hinder EPA's use of best available science and environmental regulations and it would likely diminish, rather than improve, public confidence in the integrity of EPA's scientific decision-making. Reliance on best available science is a fundamental requirement of the Clean Air Act and other environmental statutes the EPA administers. Indeed, science-based decision-making is at the very core of our shared mission as air regulators to protect public health and the environment from the harmful effects of air pollution. There is a long-term trend toward increased transparency in science including toward providing greater public access to underlying data and

analytical techniques after scientific studies are published. We think this trend is a laudable one, but complete public access to underlying data is not always possible, especially in the case of the epidemiological studies based on private health data that must remain confidential. Transparency concerns must not override EPA's obligation to consider the full range of peer-reviewed, sound, scientific research that is available and relevant to its regulatory decisions.

Full public access to underlying data and models is not necessary to assure the validity of scientific studies. Rather, the most effective assurance is the process of peer review itself, a process to which the vast majority of scientific information on which EPA relies has already been subject. When the results of a scientific study are submitted for publication, the uncertainties, assumptions, parameters and theories utilized by the scientists are laid out in the publication. Peer review analyzes all of these components to establish validity. The process of peer review

has been rigorously developed over centuries. If EPA believes the peer review process is flawed, it should explain exactly why it believes the process is inadequate and how this proposal specifically addresses those inadequacies. If adopted, the proposed rule could serve to bar EPA's consideration of relevant scientific literature and the establishment of air regulations to protect public health and the environment resulting in serious adverse effects on the nation's air program.

In a footnote in the proposal, EPA cites two D.C. Circuit cases that upheld the Agency's reliance on confidential data in setting health-based air quality standards for lead and fine particulate matter. In that footnote, EPA states that it is "proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions." The clear implication is that EPA will discard rigorously vetted scientific literature in the service of greater transparency. This would be an

abdication of EPA's legal obligations and stated intention to rely on the best available science. NACAA is also concerned with a provision that would require EPA to conduct its own "independent peer review of scientific studies underlying significant regulatory decisions." The EPA included no details about how this provision would be implemented and moreover the proposal failed to acknowledge the EPA already has institutional mechanisms to review and vet scientific information through panels of scientific experts including a Science Advisory Board and its Clean Air Scientific Advisory Committee. EPA does not explain why scientific literature that has already undergone peer review and been vetted by EPA's science advisory panel should be subjected to an additional layer of peer review. We do recognize that the proposal would allow the EPA administrator to grant exemptions to the rule's requirements on a case by case basis if he or she determines that "it is not feasible to make underlying data publically available or to conduct

an independent peer review of scientific studies." However, the rule does not include any criteria for how the administrator would make such a determination. We believe this provision would have the effect of interjecting the appearance of politics into what should be a fair and unbiased assessment. It's an opportunity for arbitrary decision-making and it is insufficient to protect against the exclusion of relevant valid scientific studies.

EPA requested comments on whether the proposal should be applied retroactively or retrospectively should they decide to adopt it. We believe the rule should not be applied retrospectively. To do otherwise would create significant regulatory uncertainty by calling into question existing standards as well as prevent state implementation plans and other decisions that are based on those standards.

In conclusion, NACAA respectfully requests that EPA withdraw the proposed rule. If the Agency does intend to update its approach to transparency

and reproducibility it should do so in consultation with the National Academy of Sciences and in the spirit of cooperative federalism EPA should also consult from the earliest stages with the state and local agencies that are responsible for implementing our nation's environmental laws. NACAA appreciates the opportunity to provide the testimony I offered today and we also intent to submit written comments to further elaborate on the concerns I discussed here. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: If Steve Malloy, Speakers 23 and 24 would come to the speaker's table. Speaker 25, Meredith McCormick, and Speaker 26, Olivia Bartlett if you would go to the on-deck seating.

MR. MILLOY: Good afternoon, my name is Steve Milloy. I publish JunkScience.com.. I am making my comments here on behalf of myself and also Dr. John Dale Dunn, who is an emergency room physician in Texas. We are here to support the proposed transparency initiative. Science transparency in EPA is long past overdue. When I first started

working on EPA issues in 1990, the main controversy with EPA science was the use of science policy and default assumptions, like linear no-threshold model of carcinogenesis. The problem wasn't necessarily the use of science policy default assumptions, the problem was, rather, the EPA's failure to disclose the nature of those default assumptions in regulatory actions. In other words, what part of the regulatory actions was science, what part was guesswork and what was politics? When I first reported on this problem from the Department of Energy in 1994, the Clinton administration tried to censor my report but they failed. But I didn't and many others didn't. So here we are, many years later, making progress on this important issue.

More recently, the major problem with EPA science has been what has become known as secret science. Since the 1990's EPA grantees like Harvard's Doug Dockery and Brigham Young University's Arden Pope, have refused to make available to the public the

raw data used in their epidemiologic studies, and this is true despite the fact that these studies were cited by EPA as the principle scientific basis for major air quality rules like those that constituted the Obama administration's war on coal.

Worse, prior EPA administrations actually aided and abetted Dockery and Pope hiding their data from public review. In 1996 and 1997 the Clinton administration refused a request of Congress. In the 2000's things got so bad Congress actually had to subpoena the Obama EPA for the data and they refused to provide it.

I can only conclude that this is because independent review of the Harvard Six Cities and the American Cancer Society line of studies would prove them to be highly problematic, embarrassing and even fraudulent. Desperate to defend the indefensible, supporters of Dockery and Pope have wrongly maintained that making the data in question public would violate medical and personal privacy rights. Nothing could be further from the

truth. For the most part, data is electronic. Scrubbed files with key data needed for independent review can easily be made available. No one -- no one -- is interested in any personal or medical data. It has no value to anyone. The State of California has made such data files available for use for many years. I know. I have obtained this data -- over 2 million death certificates to be precise -- and with it enabled research to be published that completely debunks the secret science of Dockery and Pope. Fear of exposure of their research as faulty, if not fake, is why Dockery and Pope are so scared of producing their data for independent review. To make these comments current, up to date, efforts have been made this month to obtain the Dockery and Pope data but they continue to keep their data secret. Given that the Dockery and Pope research and related PM2.5 research has been funded by taxpayers to the tune of more than 600 million dollars and then this research is used to regulate the public costing untold billions more dollars

without providing any public health or environmental benefits, the conspiratorial hiding of this secret data is more akin to crime than science.

If EPA wants to regulate, that is fine, but the basis of the regulations and the reason for the regulations must be clearly laid out so there could be full and fair debate. Harvard's Doug Dockery and Brigham Young's Arden Pope don't want independent scientists to check their work for some reason. Dockery and Pope supporters may offer whatever excuses they like but we all know what the reality is: Fear of exposure. Thanks to the Trump administration the days of secret science are coming to an end. Thank you.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker 25 and Speaker 26, Meredith McCormack and Olivia Bartlett are now onstage. If Speaker 27, Dan Byers, and Speaker 28, Antonia Herzog, would come to the on-deck seating.

MS. McCORMACK: Meredith McCormack, M-E-R-E-D-I-T-H, M-c-C-O-R-M-A-C-K. My name is Meredith

McCormack and I'm a pulmonary critical care physician at Johns Hopkins University where I care for patients and I also investigate the effects of air pollution on lung health in cohort studies of children and adults. I serve on the American Thoracic Society Environmental Health Policy Committee and I'm speaking today on behalf of the ATS, the American Thoracic Society.

The ATS is extremely concerned about the proposed EPA policy. In short, we believe this policy is not in the best interests of our profession, the patients that we serve, or the public health. The focus on transparency is highly reminiscent of the rhetoric used by tobacco lawyers decades ago. As revealed in tobacco industry documents, in 1996 a tobacco industry lawyer drafted a plan for tobacco giant, R.J. Reynolds, to combat research that documented the health effects of second-hand smoke. A tobacco industry lawyer described a plan to construct explicit procedural hurdles the Agency must follow. The memo used the same terms of transparency, sound science and calls for

reproducible science, the language that the EPA is now using in its proposed policy. While the guidance provided in that memo was intended to undermine research studies that documented the adverse effects of second-hand smoke, the recommendations provide a road map for any industry seeking to undermine science that could lead to greater regulation. While concerning, it is no accident that EPA is proposing policy once touted by tobacco industry lawyers. By proposing this policy, EPA is literally taking a page out of tobacco industry's playbook to undermine the legitimate role that science plays in public policy formation.

The ATS supports transparency in upholding scientific rigor but the approach proposed in this rule is flawed. The proposed policy would require all science and biomedical research used by the Agency in major regulatory actions to have its raw data and health records made publically available under the guise of allowing third party analysis to confirm the results of the research. This

artificial standard cannot be met without forcing the release of confidential patient information and is in direct conflict with the mandates of our institutional review boards and updated privacy laws.

As a physician, no doctor or medical society would advocate ignoring large portions of the medical literature because the underlying data were not in the public domain. Medical guidelines are based on the best available evidence: Evidence that emerges from multiple peer reviewed publications, not a single study. The medical field is rapidly moving towards increasing transparency but this cannot be applied retroactively. Is the best available science only the subset of studies whose data are available for analysis by the public? That is not the case for medical research studies and is certainly not the case for studies of environmental health effects.

EPA's new transparency standard introduces a more severe standard than the FDA uses to make decisions about the approval of drugs or that

Medicare uses to decide which treatments to cover. As a doctor I would do my patients a disservice if I ignore the best available evidence to guide my clinical decision-making. The proposed rule will allow the EPA to ignore the best scientific evidence in future decision-making about health effects of the air that we breathe and the water that we drink. The Transparency Rule fails to recognize the power of replication, a key criteria for defining the strength of scientific evidence. Replication refers to the fact that consistent findings from studies in different populations in different places strengthens the likelihood of an effect. The proposed rule would create a context for the EPA administrator to have the discretion to disregard studies that have provided the strongest scientific evidence underlying the dramatic health effects and dramatic improvements in air quality in the U.S. -- improvements that have led to measurable health benefits to our children, our patients and the general public. For the EPA to use these studies will patients

forego their confidential information? Or will the EPA now ignore the evidence from dozens of studies that have replicated findings that pollution is associated with increased risks of premature death. The Transparency Rule is unnecessary as there are processes in place to rigorously review the scientific integrity of the studies that are used in regulatory science.

In short, we fully concur with the statement from the editors of several leading scientific journals that the merits of studies relying on data that cannot be made publically available can still be judged. It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them.

In summary, this policy is issued in bad faith, is bad for science and bad for patients and bad for public health. The ATS strongly urges the Agency to withdraw this ill-conceived policy proposal.

Thank you.

MS. RADZIKOWSKI:

MS. BARTLETT: I'm Olivia Bartlett. B-A-R-T-L-E-

T-T. I'm from Bethesda, Maryland and I represent the 1200 members of Do the Most Good, Montgomery County. I am a retired PhD health scientist. For 15 years I conducted research involving human subjects and also served as a peer reviewer for both grant applications and research papers submitted for publication. For the next 30 years I oversaw the scientific peer review of thousands of applications for funding of a wide variety of health science studies including the women's health study that was mentioned by a previous speaker, so I'm very familiar with the scientific research and publication process and the rules regarding protection of human subjects. I also have asthma, as do my son and my grandson, so I am also very familiar with the impact of soot and smog in the air on the ability to breathe. EPA's mission is to protect health and the environment. I strongly oppose EPA's so-called Transparency Rule since it will restrict the scientific studies that EPA can use to carry out that mission and to set safety standards for toxic

chemicals and pollutants in the air we all breathe and the water we all drink. The proposed rule was given an appealing title but it's just a politically motivated attempt to undermine decades of progress in protecting human health from hazards, particularly small particulate pollutants in the environment, while allowing soot-producing industries off the hook. The proposed rule is seriously flawed in several important ways. First, it reflects former EPA Administrator Pruitt's woefully inadequate understanding of scientific research methods, the nature of the long-term large-scale epidemiologic studies necessary to gather the kinds of data needed to determine toxicity of a pollutant and the rigor of peer review of both research grant applications and publications. Peer reviewers carefully scrutinize the methods that will be used to collect and analyze the data before a research study is ever funded. Additional peer reviewers and different ones scrutinize the data collection and analysis methods and whether the data supports

the conclusions, again prior to publication. Studies with flaws in design, data collection or data analysis don't make it into reputable journals. The proposed rule also seriously underestimates the burden and the consequences of making all raw data publically available. Most research funding agencies and journals now have policies that require researchers to make their data available to other scientists for reanalysis, validation and meta-analyses after publication and this has already been mentioned by previous speakers. However, many studies involve sensitive and personal data that could identify individual subjects even if the subject's name and address are redacted, so releasing these data sets to the public would violate patient confidentiality rules. The proposed rule may also violate the requirements of the Clean Air Act and Clean Water Act and other standard acts already mentioned to use criteria that accurately reflect the latest scientific knowledge, the best available science and inclusive analysis of all

available studies in assessing potential effects on public health. Furthermore, the proposed rule would create an unacceptable double standard for industry-sponsored and academic research by allowing companies to shield their confidential business data, thus corporate secret science would be okay but data sets that expose individual subjects' identities would have to be made public or would be excluded from consideration in rulemaking. This ill-conceived proposed rule has been condemned by hundreds of scientists, all but one of the previous speakers today, and numerous scientific societies across health and environmental fields. Editors of prestigious journals have denounced the proposed rule and stated excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes. The bipartisan policy center, the bipartisan environmental protection network represented earlier by a speaker, the Attorney Generals of seven states and D.C. who was here earlier and

EPA's own Science Advisory Board have also denounced the proposed rule. Rather than increasing transparency, the proposed rule will hamstring EPA, eliminate some of the best science available to inform standards under the National Ambient Air Quality Standards program and jeopardize both the environment and public health by making it more difficult to adopt rules that protect public health and the environment in the future. EPA's long-standing process using data from peer-reviewed science, EPA in-house scientists and the EPA Science Advisory Board works well and mirrors the processes of other science-based agencies. The system isn't broken and doesn't need to be fixed. If EPA wants to accomplish its mission, the proposed rule should be withdrawn immediately and should not affect any rulemaking going forward or any of the studies used in periodic reanalysis of existing rules. Thank you for allowing me to comment.

MS. RADZIKOWSKI: Thank you.

MS. STOBERT: Speaker 27, Dan Byers, and Speaker

28, Antonia Herzog, if you would take seats on the stage. Speaker 29, Tess Dermbach, and Speaker 30, Mary Angly, if you would take seats in the on-deck seating.

MR. BYERS: Good afternoon. My name is Dan Byers. The U.S. Chamber of Commerce strongly supports the intent of the proposed rule and applauds EPA for addressing a long-standing problem inherent in much of its regulatory decision-making processes. While the Agency's proposed reforms are clearly controversial they are grounded in a universally-accepted democratic principle: Citizens have a right to the data and information that are used in the development of public policy. This spirit of openness with respect to the regulatory process is found throughout government. It is enshrined in statute and countless federal directives and EPA memos reinforce the principle and detailed guidance for implementing it. It is also supported by experts of all political stripes. In 2012, congressional testimony, President Obama's Science Advisor, Dr. John Holdren, unequivocally

endorsed this idea, stating that: "Absolutely the data on which regulatory decisions and other decisions are based should be made available to the committee and should be made public. The Chair of EPA's Science Advisory Board during the Obama administration subsequently echoed this sentiment. Unfortunately, while this principle is generally accepted, EPA has not followed it consistently in practice. In fact, for many years EPA has relied upon non-public data to justify its aggressive regulatory agenda. The most egregious, but certainly not the only, example of this involves two controversial studies undertaken in the 1980s that suggest a linkage between certain types of particulate matter and health outcomes. The data associated with these decades-old studies has never been made public but EPA nonetheless has used them to monetize regulatory benefit claims that dominate the communications and regulatory marketing associated with nearly all of its major rules. It's also worth pointing out here that, separate from the studies themselves, EPA's

benefit monetization is highly subjective and controversial in and of itself. For example, in 2009 the Agency modified its assumptions in a manner that resulted in a quadrupling of purported benefits without any change to the underlying data and information used to monetize it. We hope that these sorts of subjective and questionable practices will be addressed since the Agency concurrently examines the development of regulatory cost-benefit analyses. The scale of EPA's practice in this respect is mind boggling. Data compiled by the U.S. Chamber found that between 2000 and 2016, EPA issued 62 rules claiming a total of 923 billion dollars in regulatory benefits. Incredibly 898 billion of these benefits, or 97%, were monetized based on the non-public data associated with PM2.5. In fact, these benefits comprise nearly 80% of all regulatory benefits across the entire federal government. Even though the vast majority of these rules were not intended to address PM2.5, and even though the vast majority of their

corresponding claim benefits came from areas of the country already deemed safe and in compliance with the standard, the Agency repeatedly touted these figures to build public support for its regulations. It's one thing to be cavalier about transparency principles when their application has little or no import to public policy. The federal rules that impact millions of people and billions of dollars should be held to a higher standard. For these reasons, we applaud EPA's effort to establish and meet a higher standard and we commend the Agency for doing so through the formal public comment and rulemaking process rather than simply instituting a new policy. As EPA makes clear throughout the rule, these changes will require considerable effort and cooperation, and despite suggestions otherwise, the proposal clearly states that its aim is not to exclude science but rather to ensure: "That over time more of the data and models underlying the science that informs regulatory decisions is available to the public for validation." And, to more broadly

quote: "Change Agency culture and practices regarding data access." The outcome will not just lead to better public policy, it will improve the integrity of the rulemaking process and in doing so increase public trust in, and support for, EPA itself. Whether you agree with the administration's regulatory approach or not, that is a good thing. With that fundamental background in mind I will close by calling attention to six high-level areas that warrant emphasis and attention as the Agency works to finalize the rule. These are elaborated on in my written comments.

1) Protect sensitive information;

2) Formally coordinate with other agencies working to address similar regulatory transparency challenges;

3) Develop further guidance and processes for employing the administrator's exemption authority under the rule;

4) Consider alternative approaches to balancing trade-offs between goals related to

transparency and maximizing the quantity and quality of information relied upon. For example this could include assigning greater decision-making weight to publically available data while still allowing for the consideration of nontransparent data;

5) Where possible, work to protect and de-identify sensitive information to allow for its continued use in regulatory decision-making, and;

6) Ensure that relevant transparency information is incorporated into public communications and marketing materials associated with regulatory initiatives. Thank you for your time and consideration today.

[Substitution of panel members.]

MS. HUBBARD: Thank you.

MS. HERZOG: Hello, my name is Antonia Herzog, H-E-R-Z-O-G, and I am a scientist with a doctorate in Physics. I am particularly concerned about preserving the scientific integrity of the EPA. I work in the Environment and Health Program at Physicians for Social Responsibility, a nonprofit

organization here in D.C. with chapters in multiple states across the country and over thirty thousand members and activists around the country. Our mission is to protect human life from the gravest threats to health and survival; we number environmental pollution among those key threats. PSR would like to express its strong opposition to the EPA's proposed rule, "Strengthening Transparency in Regulatory Science." This proposed rule could arbitrarily exclude many important scientific studies-including thousands of public health and epidemiological studies that the Agency uses to make informed policy decisions regarding major public health and environmental laws. While it pretends to be about "transparency", the policy actually will limit the Agency's ability to use the best available science thereby weakening protections for public health and the environment. In essence it could censor and block much of the peer reviewed scientific research that has allowed us to address many serious environmental health threats over the decades.

EPA's proposed rule would place crippling restrictions on the use of data the Agency would accept in the rulemaking process by ultimately requiring investigators to divulge personal information about the participants in research studies. Scientific studies that failed to meet this criterion would not be acceptable to the Agency. At present, this kind of information must be kept confidential according to the generally accepted rules that govern the conduct of research that must be adhered to by agencies of the federal government and institutions that receive federal funds. A particular example that is concerning to me and is particularly relevant today where it's so hot outside and the air quality is questionable, is the Clean Air Act, a bedrock environmental law that protects us from dangerous air pollutants. It is such a critical health protection that would be endangered under this proposed rule because it relies on a longitudinal epidemiologic study of thousands of individuals. This includes the National Ambient Air Quality

Standards (NAAQS) in the Clean Air Act. These standards address six major classes of common air pollutants, including standards for fine particles {PM2.5), and these are the backbone of the U.S. air quality management system.

The Clean Air Act specifies that new or revised NAAQS be based on scientific criteria that "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air." EPA has relied largely on community epidemiology and controlled human studies in establishing the specific pollutant levels and averaging times for NAAQS. If these studies were excluded by the EPA restrictions it would greatly reduce the availability of information that has proved to be significant in assessing the consistency and coherence of the evidence upon which the standards are based and would certainly weaken the scientific basis for maintaining or strengthening

those current standards. If the proposed rule is approved, we could lose the Clean Air Act's sweeping improvements to the air we breathe that we've benefited from over the last several decades thereby putting thousands of lives that are saved each year at risk, because EPA will no longer be able to use key scientific research.

PSR's mission is very similar to EPA's stated mission "to protect human health and the environment." To accomplish these objectives, we must protect the scientific integrity of the EPA. Physicians for Social Responsibility thus, strongly opposes the EPA's deceptively named proposal, "Strengthening Transparency in Regulatory Science." Thank you.

MS. HUBBARD: Thank you.

MS. STOBERT: Speaker 29, Tess Dernbach, and Speaker 30, Mary Angly. If you come to the speakers' table. Is Mary Angly in the room? Okay, we'll come back to her at the end.

MS. DERNBACH: My name is Tess Dernbach, T-E-S-S,

D-E-R-N-B-A-C-H. I am a third-year law student at Columbia Law School and a legal intern at Earthjustice, speaking on behalf of Earthjustice. EPA's proposed rule, "Strengthening Transparency in Regulatory Science," requires a choice between breaching medical privacy or ignoring data for rulemaking decisions altogether. Breaching a patient's medical confidentiality can have severe and wide-ranging consequences for patients' lives and livelihoods. Various groups have often tried to access patient data for retaliatory purposes. For example, when pork industry associates tried to access the identities of individuals who had participated in a study by the University of North Carolina Professor Steve Wing, about the harmful health impacts of hog farming, or when the Department of Justice tried to access names of women who had late term abortions for use in litigation challenging the Partial Birth Abortion Ban Act. Employees' health information can be and is used against them by employers as an excuse for termination or other poor treatment. Moreover,

when the medical confidentiality of research participants is breached, people are deterred from participating in research altogether. Medical confidentiality is a necessary element of modern medicine. Patients must feel safe telling their doctors the most intimate details of their lives. The expectation of confidentiality fosters openness and trust between doctors and patients and is crucial to the delivery of medicine and conducting clinical research. Courts recognize, too, the importance of medical confidentiality and privacy. In 1928, Justice Brandeis described the right of privacy as: "The most comprehensive of rights and the right most valued by civilized men." At least five circuit courts have recognized an individual's constitutional interest in or right to the privacy of their medical information. In Farnsworth v Procter and Gamble in the 11th Circuit, the court recognized that: "Even without an express guarantee of confidentiality, there is still an expectation, not unjustified, that when highly personal and

potential embarrassing information is given for the sake of medical information it will remain private." This right to medical privacy can extend to beyond publication of medical data to situations where medical information is available to those without a legitimate interest in it. See, for example, Tucson Women's Clinic v Eden in the 9th Circuit, where the court observed that even if safeguards against public disclosure were adequate, the lack of safeguards against release of information to government employees who have no need for the information could create a violation of the right to privacy.

The EPA claims, vaguely, that confidential data will be protected by redaction or de-identification. However, these mechanisms are entirely inadequate to maintain patient confidentiality. Latanya Sweeney, a Harvard Professor of Government and Technology, found in her study simple demographics often identify people uniquely that she was able to identify 87% of people in the United States with only their

gender, zip code and birth date. She has also found particular problems in patient confidentiality de-identification observing that in many healthcare data sets there will be unique data about people that can be used to identify them even when they are not explicitly identified in the data set. Sweeney found that even without identifying data in health data sets: "The remaining data can be used to re-identify individuals by linking or matching the data to other databases or by looking at unique characteristics found in the fields and records of the database itself."

Paul Ohm from the Georgetown Law School found in his pivotal work: Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization, that using traditional, personally identifiable information focused anonymization techniques, any data that is even minutely useful can never be perfectly anonymous. These studies seriously undermine government claims that de-identifying data will provide adequate privacy for

patient data contained within research studies. Because of these reasons and those given before me, I strongly urge EPA to revoke the proposed rule immediately. Thank you.

MS. HUBBARD: Thank you.

MS. ANGLY: Hello, my name is Mary Angly and I'm interning for the organization Physicians for Social Responsibility and I've come to speak against the proposed rule, "Strengthening Transparency in Regulatory Science." Medical studies, clinical reports, and real-world field studies all include data and information that cannot be made public without violating confidentiality in patient protection laws. The proposed rule implies that these studies are not transparent because researchers necessarily suppress names and other identifying information about patients whose health information is relevant to study findings. Releasing individual participants' data to the public would violate confidentiality requirements legally mandated by the IRB and/or by HIPAA. By restricting these

studies, the proposed rule would essentially force the EPA to base many of its regulatory decisions on industry-sponsored studies and this rule could have huge environmental and public health implications. Despite a supposed scientific process, the funding source for a study can have significant implications on study findings. For example, in a review of research into the health effects of EPA an evaluation of 115 relevant studies was conducted in 2009. The review found that 94% of the publically funded studies found that chemicals have harmful effects whereas none of the industry-backed studies found these same findings. This is a huge disparity that cannot have occurred due to chance alone. Successful regulatory policies can have huge and quantifiable effects on exposure levels in human health. Biannually, the CDC collects data recording the blood and urine levels of 265 chemicals in people across the country. Longitudinal data can be used to visualize falling exposure levels and thus not measure the impact of a policy. For instance,